

Notice of Allowability

Application No.

09/997,868

Examiner

Stephen Gucker

Applicant(s)

GORMAN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/25/06.
2. ☒ The allowed claim(s) is/are 32-37, renumbered as 1-6, respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 8/24/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT & REASONS FOR ALLOWANCE

1. The restriction requirement filed on July 7, 2005, is **WITHDRAWN**. SEQ ID NO:59 and SEQ ID NO:61 are being rejoined with SEQ ID NO:60 as part of the same invention.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Katherine M. Kowalchuk on 1/9/06.

An examiner's amendment to the record appears below.

In the claims:

Replace claim 32 with the following:

32. (Currently amended) An isolated animal host cell that is not naturally capable of forming secretory granules and that comprises a first transfected nucleic acid encoding a prorelaxin polypeptide comprising an amino acid sequence of SEQ ID NO:59, SEQ ID NO:60, or SEQ ID NO:61, wherein the prorelaxin polypeptide comprises three polypeptide chains A, B and C and comprises two dibasic enzyme cleavage sites, one positioned at a C-A peptide junction and one positioned at a C-B peptide junction, and wherein the prorelaxin polypeptide exhibits a hormonal activity of relaxin; and a second transfected nucleic acid encoding an enzyme that is capable of cleaving the prorelaxin polypeptide to form a mature two chain relaxin polypeptide.

3. The following is an examiner's statement of reasons for allowance: the closest prior art of record (Hudson in view of Mulvihill), while making the instant invention obvious to try, does not raise the invention to the level of obvious to succeed for the following reasons. Marriott et al. (*Molecular Endocrinology*, Vol. 92, 1992, pages 1141-1450, IDS filed 6/5/02) disclose that prorelaxin is normally processed in the specialized secretory granule (originating partly from the RER), and not the comparatively nonspecialized secretory vesicle from the Golgi apparatus, as is required by the

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limitations of instant claim 32. As Marriott et al. disclose, the enzymes isolated from secretory granules (such as PC1) have been shown to have pH and calcium requirements that differ from conditions found within the Golgi. In addition, PC1 is normally anchored within secretory granules and, therefore, found concentrated with regard to its substrates (such as prorelaxin). Given these parameters, the obvious to succeed threshold has not been met, and Marriott et al. even concede that the incomplete processing they observed may be due to these and other factors, such as incorrect folding of the prorelaxin when processing occurs outside of the secretory granule (page 1447). Also, see applicant's arguments and remarks filed 8/24/06, especially page 10.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Janet Andres, can be reached at (571) 272-0867. The fax phone number for this Group is currently (571)-273-8300.



Stephen Gucker

January 11, 2007



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER